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EXAMINER	
COLEMAN, BRENDA LIBBY	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,012	MA ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/3/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of the composition and method of use claims is not adequately enabled solely based on the bacterial activity provided in the specification. Instant claim language embraces disorders not only for treatment but for prophylaxis which is not remotely enabled. It is presumed in the prophylaxis of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop a disease associated with methicillin-resistant staphylococcus aureus (MRSA) infections. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the variables R^2, R^3, R^4 and R^5, which are not defined within claim 1.

b) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of A^1, B^1, D^1 and E^1, which includes two of each of the moieties $-OR^2$ and $-SR^2$ in line 11 and again in line 14 of page 29.

c) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition where A^1 and D^1, A^1 and E^1, B^1 and D^1, or the second occurrence of B^1 and D^1 in line 17 of page 29.

d) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by "hydroxyl protecting group" in the definition of R^p.

e) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of the substituents on the aryl, heteroaryl and heterocyclyl or R^1, which includes the moiety (O). See line 39 on page 30.

f) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the variable $R^{35'}$, which is not defined within claim 1.

g) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of the substituents on the alkyl, which includes the moiety (O). See line 48 on page 30.

h) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of R^{35} and R^{36}, which is defined as "independently selected alkyl". See line 56 on page 30.

i) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of R^{40}, where R^{40} is inidazolidinyl. See line 62 on page 31.

j) Claims 1, 4 and 5 are vague and indefinite in that it is not known what is meant by the definition of the substituents on the R^{40} moieties, which includes the moiety (O). See line 67 on page 31.

k) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of R^1, which is not stated in the form of a proper Markush grouping, i.e. selected from the group consisting of aryl, heteroaryl.

l) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of heteroaryl in R^1, which is not stated in the form of a proper Markush grouping, i.e. is pyridyl and quinolinyl.

m) Claim 3 is vague and indefinite in that it is not known what is meant by the definition of heteroaryl in R^1, which is not stated in the form of a proper Markush grouping, i.e. is pyridyl and quinolinyl.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Or et al., U.S. Patent No. 5,866,549 and U.S. Patent No. 6,075,133. The generic structure of U.S. '549 encompasses the instantly claimed compounds (see Formula IV, column 2) and for the same uses as claimed herein. Examples in column 28, lines 54-61 and 64-65 and column 29, lines 1-2, 5-6, 9-14, 37-40 and 45-46 differ only in the nature of the R substituent. Column 4, line 53 through column 7, line 5 defines the substituent R as (1) methyl substituted with a moiety selected from the group consisting of CN, R, ...(6) C_4-C_{10}-alkenyl substituted with one or more substituents.....(k) aryl, (l) substituted aryl, (m) heteroaryl, (n) substituted heteroaryl....(8) C_3-C_{10}-alkynyl substituted with one or more substituents.....(b) aryl, (c) substituted aryl, (d) heteroaryl, (e) substituted heteroaryl. pounds of the instant invention are generically embraced by U.S. '549 in view of the interchange ability of the R substituent of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example $-CH_2CH=CH-CH_2$phenyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Applicants' should also note that claimed subject matter is involved with U.S. Patent No. 6,075,133. Two patents cannot issue to the same invention. Applicants' are required to show patentable differentiation of the claimed subject matter.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-6 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of copending Application No. 10/361,912. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-12 of U.S. Patent No. 6,075,133. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula IV embraces the compounds, compositions and method of use of the compounds of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
March 5, 2004